

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

*County of Lake, Ohio v. Purdue
Pharma L.P., et al.,*
Case No. 18-op-45032 (N.D. Ohio)

*County of Trumbull, Ohio v. Purdue
Pharma, L.P., et al.,*
Case No. 18-op-45079 (N.D. Ohio)

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

CVS'S TRIAL BRIEF

Pursuant to the Civil Jury Trial Order, Doc. 3758 at 6, Defendants CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS TN Distribution, L.L.C., Ohio CVS Stores, L.L.C., and CVS Pharmacy, Inc. (together, "CVS") hereby submit their trial brief.

PRELIMINARY MATTERS

This trial brief is submitted in accordance with Special Master Cohen's instruction that the parties follow the Court's guidance in Track One-A to provide "concise trial briefs of no more than 10 pages that describe how the parties intend to prove or defend their case." Minute Order, Sept. 17, 2019. As a result, this brief does not address legal issues previously raised with the Court. Nor does it raise additional legal issues that may arise before or during trial. CVS will raise, re-raise, and present argument on these legal issues at the appropriate time, including, without limitation, in Rule 50 and 59 motions.

Consistent with the Court's directive for "concise" trial briefs, this submission does not contain an exhaustive presentation of CVS's anticipated defense at trial. Instead, it identifies

certain issues that CVS anticipates may arise. The arguments and evidence that CVS ultimately presents at trial are too expansive for a short trial brief and will necessarily depend on what theories and evidence Plaintiffs present at trial. CVS cannot predict how Plaintiffs will present their case. For instance, Plaintiffs have served an exhibit list with more than 4,500 entries, which equates to tens of thousands of documents in total, and Plaintiffs will be supplementing some of their expert reports to address “notes” evidence that the Court recently ordered to be produced and for which discovery is not yet complete. CVS also will be forced, over its repeated objections, to limit its defense at trial due to the trial time and witness restrictions imposed by the Court. CVS continues to object to these restrictions and reasserts its objections here. For present purposes, CVS submits this trial brief mindful that it is not comprehensive, reflects a sampling of issues, and without prejudice to its right to supplement and revise its trial presentation and to offer different or additional evidence.

SUMMARY OF CERTAIN DEFENSE EVIDENCE

Plaintiffs’ allegations against CVS are completely unfounded. The evidence presented at trial will show not only that CVS met the legal requirements for distributing and dispensing prescription opioid medications in Lake and Trumbull Counties, but that it exceeded them. The evidence also will show that CVS was not a cause of opioid abuse and addiction in the counties.

The ultimate question to be decided at trial is whether CVS engaged in wrongful conduct that caused a public nuisance that exists in Lake and Trumbull Counties *today*. To prevail on this claim, Plaintiffs must show that CVS’s conduct has resulted in an unreasonable interference today with a right common to the general public and the community at large. *Kramer v. Angel’s Path, L.L.C.*, 882 N.E. 2d 46, 52 (Ohio Ct. App. 2007) (“A public nuisance is an unreasonable interference with a right common to the general public. A public nuisance will not arise because a large number of people are affected; rather, it arises only when a public right has been

affected.”) (internal citations and quotations omitted). Conduct that is expressly authorized by a statute or regulation cannot create a public nuisance. *Brown v. Scioto Cty. Bd. of Commrs.*, 622 N.E.2d 1153, (Ohio Ct. App. 1993) (“[C]onduct which is fully authorized by statute or administrative regulation is not an actionable tort. This is especially true where a comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct exist.”).

The evidence presented at trial will show that prescription opioid medications are approved by the U.S. Food and Drug Administration as being safe and effective, and that they help treat many patients. The evidence will show that the U.S. Drug Enforcement Administration (“DEA”) determined the volume of prescription opioid medications that would be manufactured each year, and that the volume was never exceeded. The evidence presented at trial will show that CVS did not manufacture prescription opioid medications and that it did not market such medications to doctors. The evidence also will show that CVS did not write prescriptions for opioid medications. Rather, doctors who are licensed by the DEA and the State Medical Board of Ohio wrote the prescriptions.

Subject to a pending motion *in limine* (Doc. 3837) and over CVS’s prior objection (Doc. No. 3773), Plaintiffs’ claims at trial will concern, in part, CVS’s distribution of prescription opioid medications. CVS distributed only to its own pharmacies. CVS did not distribute to rogue pain clinics, rogue internet pharmacies, or dispensing practitioners. CVS also has never distributed prescription opioid medications that are classified as Schedule II under the Controlled Substances Act. Accordingly, the only prescription opioid medications at issue that CVS has ever distributed are hydrocodone combination products (“HCPs”). CVS stopped distributing those medications in October 2014 when they were reclassified as Schedule II. Plaintiffs will not

be able to show that any HCPs distributed by CVS to its pharmacies in Lake and Trumbull Counties before October 2014 were diverted, let alone that they were a substantial factor in causing a public nuisance that exists in the counties *today*—seven years after CVS stopped distributing.

Regardless, CVS will present evidence at trial showing that it complied with the DEA requirement that it “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” 21 C.F.R. § 1301.74(b). The CVS distribution centers that shipped HCPs to CVS pharmacies in Lake and Trumbull Counties operated a manual system for reviewing orders. Each order was reviewed by CVS employees who picked and packed the orders, and they brought any concerns they had with an order to the attention of their supervisors. This manual system was supplemented by a data report, generated and reviewed monthly or quarterly, that identified potential ordering irregularities. Beginning in or around 2009, CVS also operated a computerized system based on an algorithm. Each HCP order was run through the algorithm, and each order that scored above a certain threshold was reviewed by a CVS employee. CVS may present expert testimony from a former high-ranking DEA official, Robert Hill, on the sufficiency of these systems.

Plaintiffs’ claims at trial also will concern CVS’s dispensing of prescription opioid medications. There are fourteen CVS pharmacies that operate in Lake and Trumbull Counties; a fifteenth closed in 2012. The evidence presented at trial will show that at all times these pharmacies were registered with and regulated by the DEA and Ohio Board of Pharmacy (the “Ohio BOP”), that they were inspected by the Ohio BOP, and that at all times they were in good standing with the DEA and Ohio BOP. They never were disciplined or sanctioned by the DEA or the Ohio BOP for filling a prescription for an opioid medication that they should not have

filled. In fact, the evidence presented at trial will show that CVS pharmacies in Lake and Trumbull Counties cooperated with and assisted law enforcement in identifying individuals who presented fraudulent prescriptions.

The applicable DEA regulation on filling prescriptions states that a pharmacist shall not “knowingly fill[]” a prescription that is not written “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 31 C.F.R. § 1306.04(a). CVS policy in this regard also has been clear and unequivocal: a pharmacist shall not fill a prescription for a controlled substance when he or she knows it was not written for a legitimate medical purpose. Plaintiffs will not be able to show that a CVS pharmacist in Lake and Trumbull Counties filled any prescription for an opioid medication that he or she knew was not written for a legitimate medical purpose. Plaintiffs have the burden of proof, yet their witness list does not contain a single doctor who wrote a prescription that they contend should not have been filled by CVS and contains only one CVS pharmacist who has worked in the counties. The evidence will show that CVS pharmacists in Lake and Trumbull Counties reviewed prescriptions for potential red flags and refused to fill prescriptions when any such concerns could not be resolved.

CVS also will present evidence of the computer systems, technology, and data analytics it has implemented that, among other things, supply CVS pharmacists with information and assist them in reviewing prescriptions. Plaintiffs themselves repeatedly highlight one such CVS program: a data-driven program to review and investigate doctors and, where appropriate, to block their prescriptions from being filled at all CVS pharmacies. This program, which was the subject of a New England Journal of Medicine article, was created by CVS from whole cloth and is not required by any federal or state law. CVS will present evidence on this technological

program and others that aid its pharmacists in determining whether to fill prescriptions and that monitor dispensing at its pharmacies.

It appears that Plaintiffs will build their case around supposed “red flags.” The evidence presented at trial will show, however, that Plaintiffs “red flags” are not red flags at all. A determination of the presence or absence of red flags depends on the totality of the particular facts and circumstances of each prescription and, ultimately, on the professional judgment of a pharmacist. Plaintiffs’ “red flag” evidence—generated by one of its experts—does not consider the totality of the facts and circumstances of each prescription. Indeed, Plaintiffs have conceded that the “red flag” prescriptions they have identified for CVS were not necessarily illegitimate prescriptions and were not necessarily diverted.

In addition to testimony from CVS employees, CVS may present expert testimony on these dispensing issues, including without limitation testimony from former DEA official Robert Hill, current pharmacy professor Kimberly Burns, and data experts.

Finally, the evidence presented at trial will show that to the extent there is a problem with opioid abuse and addiction in Lake and Trumbull Counties, it was not caused by CVS but by other actors who are not parties to this trial. This includes without limitation criminal drug dealers and heroin traffickers. The evidence will show that opioid abuse and mortality in Lake and Trumbull Counties primarily has been the result of illicit opioids, such as heroin and illicit fentanyl. CVS of course did not distribute or dispense heroin or illicit fentanyl.

EVIDENTIARY ISSUES

CVS cannot anticipate every evidentiary issue that will arise at trial, and CVS does not endeavor to identify every such issue here. CVS does anticipate, however, that the following evidentiary issues may arise at trial and, depending on how they are resolved, may have a significant impact on CVS’s defense and on the overall conduct of the trial:

- Temporal Scope. The question presented at trial is whether CVS engaged in wrongful conduct that caused a present-day nuisance in Lake and Trumbull Counties, yet Plaintiffs will attempt to introduce evidence related to shipments made and prescriptions filled by CVS ten and fifteen years ago. Not only is such evidence irrelevant to the conditions that exist in the counties today, it likely will be cumulative of evidence related to more recent shipments and prescriptions, and it will unnecessarily prolong the trial because CVS will need to present evidence and call witnesses to defend such remote conduct.

- Geographic Scope. Although this case involves Lake and Trumbull Counties, Plaintiffs will attempt to introduce evidence related to conduct that occurred in other jurisdictions hundreds or thousands of miles away. Such evidence is not relevant, is unfairly prejudicial, and will confuse or mislead the jury. Allowing Plaintiffs to present such evidence also will unnecessarily prolong the trial because CVS will need to present evidence and call witnesses to defend conduct that had no impact on Lake and Trumbull Counties.

- Metrics and Staffing. At the pharmacy level, this case concerns the dispensing of prescription opioid medications. Plaintiffs may attempt to introduce evidence related to performance metrics that have nothing to do with the dispensing of prescription opioid medications and evidence related to the staffing of CVS's pharmacies. Such evidence not only is irrelevant, it is unfairly prejudicial and would result in a mini trial on CVS performance metrics and staffing, further prolonging the trial.

- DEA Settlements. The Court previously ruled that it would consider the admissibility of DEA settlements as they arise in the context of the trial. Doc. 3546 at 31. Plaintiffs likely will attempt to admit evidence of DEA settlements involving CVS pharmacies outside Lake and Trumbull Counties. These settlements should not be admitted. They are not

relevant—they involve different pharmacies, different pharmacists, and different prescriptions written by different doctors. They also are highly prejudicial and would once again force CVS to devote precious trial time to defending conduct occurring in other jurisdictions that had no impact on Lake and Trumbull Counties.

JURY INSTRUCTIONS

Finally, CVS requests an opportunity to be heard at the September 28 pretrial conference on the Court's jury instructions. While CVS has preserved its objections to the instructions in prior submissions, it would appreciate the opportunity to provide the Court with additional information on the basis for its objections and to explain why the instructions in their current form are erroneous and would unfairly prejudice CVS.

Dated: August 19, 2021

Respectfully submitted,

/s/ Eric R. Delinsky

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